COMMITTEE ON GOVERNMENT REFORM

CONGRESSMAN TOM DAVIS, CHAIRMAN



<u>NEWS RELEASE</u>

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Chairman Davis Applauds House Passage of Project Bioshield Act

Washington, D.C. – House Government Reform Committee Chairman Tom Davis (R-VA-11th) today lauded House passage of H.R. 2122, the "Project Bioshield Act," critical legislation that gives the government the necessary tools to develop and purchase vaccines and other drugs to protect Americans in the event of a bioterrorist attack.

Davis released the following statement on the legislation, which the Government Reform Committee approved on May 22, 2003:

"The President first announced this proposal during his 2003 State of the Union address. It is a cornerstone of the Administration's strategy to prepare our nation against the possibility of a bioterrorist attack.

"As we tragically learned during the Fall of 2001, our nation is vulnerable to biological terrorism. Letters laced with anthrax caused the deaths of five individuals and thousands more had to be treated. The death toll could have been higher if there had not been effective countermeasures to treat that particular form of anthrax.

"Unfortunately, there has been little progress in treatments for other deadly diseases like smallpox, Ebola, and plague, which affect few, if any Americans. The reality is there is little manufacturer interest in developing necessary treatments for these diseases because no significant commercial market exists outside the government.

"The absence of financial incentives has provided drug companies with little reason to make the substantial investment that is required to develop treatments to these deadly diseases. Should the United States be attacked with these deadly pathogens, however, the need for vaccines, tests, and treatments would be great and immediate. H.R. 2122 is designed to ensure that the United States is prepared.

"The bill provides the Secretary of Health and Human Services with a number of flexible acquisition tools, based on existing streamlined procedures, to promote research and development and procurement of necessary drugs and vaccines. These tools are instrumental to the success of the bioshield program.

"For example, the bill increases the simplified acquisition threshold for research and development projects from the current level of \$100,000 to \$25 million. This increase will help the Secretary promote sophisticated research and development projects by streamlining the acquisition process.

"The bill also authorizes the procurement of biomedical countermeasures, again using tailored flexible acquisition tools, for inclusion in the nation's stockpile using a special reserve fund. The Secretary would also have expedited authorities to award research grants and to hire technical experts and consultants.

"During national emergencies, the bill would permit the government to make available new and promising treatments prior to approval by the Food and Drug Administration.

"The Government Reform Committee, which I chair, held a hearing to examine the bioshield proposal on April 4, 2003. Witnesses from the government, academia, and pharmaceutical and biotech companies were supportive of the bill. They all recognized the need to create incentives for manufacturers to develop biomedical countermeasures.

"Our Committee favorably approved the bill on May 22. Working in a bipartisan fashion, we unanimously adopted some amendments to ensure greater accountability in the acquisition process and to clarify the circumstances when biomedical countermeasures can be procured.

"Specifically, the amendments we approved permit the use of simplified acquisition procedures only when the Secretary of Health and Human Services determines there to be a pressing need for the procurement of a specific countermeasure.

"The bill commits decisions about research and development projects to the discretion of the Secretary of HHS. However, we approved an amendment that preserves a limited right for companies to appeal to the General Accounting Office contracting decisions made by the Secretary. Appeals could <u>not</u> be used to stall the research and development procurement process.

"We also made some technical changes to clarify the circumstances when the Secretary of HHS could use other than fully competitive procedures for research and development and production contracts.

"This is a critically needed bill that serves a compelling national interest."